



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 02 2010

I-009033-D-0115-OT

U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief, AADAP
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Amended food-use authorization for delta smelt treated with oxytetracycline hydrochloride

Dear Dr. Erdahl:

You are authorized an additional species, delta smelt (*Hypomesus transpacificus*), for human and animal food use. Edible tissues derived from experimental animals treated under the conditions described in this letter may be marketed for human consumption, for use in animal feeds, or released into public waters for possible human consumption. This authorization is in response to your submission dated March 16, 2010 (D-0115). This amended authorization for the use of oxytetracycline hydrochloride soluble powder in delta smelt (*Hypomesus transpacificus*) is consistent with the public health. Previous authorizations under this INAD are superseded with the exception of the D-0117 authorization for skeletal marking.

AMENDED FOOD-USE AUTHORIZATION

DRUG IDENTITY	Oxytetracycline hydrochloride
Dosage Form	Soluble powder
SPECIES	Marine and freshwater finfish
Class	Salmonidae, Acipenseridae, Catostomidae, Centrarchidae, Cyprinidae, Cyprinodontidae, Esocidae, Ictaluridae, Percidae, Poeciliidae, <i>Paralichthys</i> spp., <i>Seriola</i> spp. <i>Centropristis striata</i> (black sea bass), <i>Scorpaenichthys marmoratus</i> (cabezon), <i>Dicentrarchus labrax</i> (European sea bass), <i>Sparus aurata</i> (gilthead seabream), <i>Polyodon spathula</i> (paddlefish),

	<i>Atractoscion nobilis</i> (white sea bass), <i>Hypomesus transpacificus</i> (delta smelt)
Number of Animals	2 million (begin counting with D-0098 dated October 1, 2007)
PERMITTED DOSING REGIMEN	
Maximum Dose (or range)	20 mg/L
Route of Administration	Immersion
Frequency and Duration of Dosing	Single treatment for 1 hour or Multiple treatment: One hour daily for 1 - 4 consecutive days
MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	21 days for single treatment. No withdrawal period is required for fish that will not be catchable for 21 or more days after release, or are illegal for harvest. 60 days for multiple treatments. No withdrawal period is required for fish that will not be catchable for 60 or more days after release, or are illegal for harvest.
MINIMUM INVESTIGATIONAL MILK DISCARD PERIOD	Not applicable
OTHER RESTRICTIONS OR CONDITIONS	None

This food-use authorization only applies to the treatment regimen stated above. Any change in the dosage regimen or the combining of this treatment with any other drug will require a separate food-use authorization. Drugs given to control animals must be administered in full compliance with the currently approved use. Your investigators should be made aware of their responsibilities under 21 CFR 511.1(b)(7)(ii) and (c)(1).

In addition, we remind you that a sponsor must submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals (see 21 CFR 511.1(b)(4)). You may file the notice of the drug shipment electronically to the Center for Veterinary Medicine (CVM). Please refer to the Center's electronic submission information on the CVM website at <http://www.fda.gov/cvm/esubstoc.html>. Alternatively, you can send three copies of the completed form to CVM. Furthermore, we note that clinical tests conducted under the provisions of this letter do not exempt investigational animals and their products from compliance with any other applicable inspection requirements (see 21 CFR 511.1(b)(5)(iii)).

INVESTIGATIONAL LABELING

The appropriate investigational labeling required under 511.1(a) or (b) must be affixed to your investigational drug product before shipping your drug product for studies conducted under 21 CFR 511.1(a) or (b), respectively. Affix the investigational label to each individual drug container.

COUNTING NUMBERS OF FISH

This authorization replaces our authorization letter dated March 16, 2010 (D-0113). From here forward, please reference the current authorization (D-0115) and continue counting the number of fish used since October 1, 2007 (D-0098). Please count the number of fish treated for bacterial disease separately from those marked.

Please provide the total number of fish used towards this authorization in your annual reports. We remind you that a fish treated more than once still only counts as a single fish toward the authorization.

Additional numbers of fish may be requested in the future. A request for additional fish should be made with sufficient lead time to allow us to process an amended authorization.

ANNUAL REPORTS

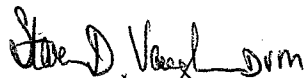
We remind you of the continued necessity to provide annual reports under the FDA/CVM Aquaculture Workload Plan. Your annual report should include: a) a brief summary of the past year's activities and accomplishments in each of the INAD technical sections; b) certification of accountability of all drugs shipped under the INAD, records maintenance for FDA inspection, and compliance with the provisions of 21 CFR Part 511, including notification of adverse effects relative to humans, target animals, or the environment resulting from the use of the investigational drug; c) a list of all investigators, facilities, and species treated; and d) a copy of the current study protocol(s) noting any modification or revision. We recommend that any changes to pivotal study protocols be reviewed by CVM prior to initiating further investigations.

ADDITIONAL COMMENTS

1. In order for us to complete our files, the disposition of all investigational animals and unused drugs must be reported to this office. Please refer to this letter by date and INAD number when reporting the details of clinical investigations or the disposition of investigational animals.
2. Promptly report to this office any adverse reactions that may suggest significant safety hazards.
3. You should obtain a material safety data sheet (MSDS) for the investigational drug and follow the information in the MSDS to protect all individuals who may be exposed to the investigational drug.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Cindy L. Burnsteel, Director, Division of Therapeutic Drugs for Food Animals at 240-276-8341.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven D. Vaughn, DVM". The signature is fluid and cursive, with the "DVM" part being more distinct.

Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine